

Merck Serono

Living science, transforming lives



ADaM on a Diet Preventing Wide and Heavy ADs



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Standard Data – Clear benefits

- Easier automation / tools
- Better **communication** about the data
 - Reviewers
 - Service Providers
 - Partners
- Easier **sharing** and **inheriting** of work

SDTM and ADaM – Submission formats

- ADaM datasets:
 - Analysis Ready
 - Focus on Key Results
 - Not every listing in a CTR
- Use for other purposes than submission too
 - Work in (near) ADaM always
- Some companies: ADs for all deliverables
 - Retrospective vs. Prospective

SDTM: Mature standard

- Lots of standard domains available
- Something does not fit?
 - Supplemental: --SUPP
 - New domain: Follow classification and pick
 - Event: --TERM
 - Intervention: --TRT
 - Finding: --TEST(CD)

SDTM and ADaM

- SDTM

- Model: version 1.2

- IG: version 3.1.2

- ADaM (Dec 2010)

- Model: version 2.1

- IG: version 1.0

ADaM: Two models, some drafts

- ADSL – Subject Level Analysis Dataset
- BDS – Basic Data Structure

- Draft ADAE
 - Extend to General Occurrences AD
- Draft ADTTE
 - Actually a case for BDS

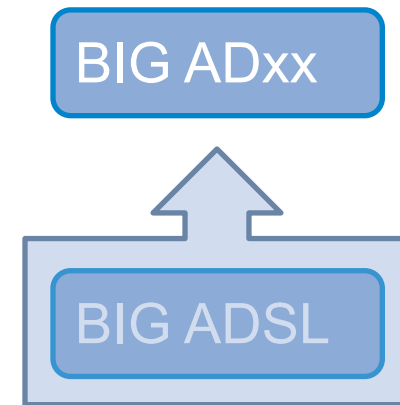
- Nice examples document out just now

ADaM: Info not described in the models

- A lot of information not described in the model
- Subject Level Information
 - Often ends up in ADSL
 - Additional variables
 - Often copied to all other analysis datasets
 - ⇔ CDER common issues document
 - Though: ADs for all outputs

- Bearing in mind:

- ADaM ADs not only for submissions
- ADs for all deliverables



ADaM: Info not described in the models

- **Baseline information**
 - Height – Weight
 - BMI – Study specific, lab baselines
- **Categories of Baseline information**
- **Discontinuation Reasons**
 - Treatment
 - Study
- **Treatment Duration**
- **Smoking, Drinking, other Risk Factors**
 - durations – frequencies – ...

Plug it all onto ADSL?

- All such subject level information can go on ADSL
- Naming convention to adhere to
- What is **still standard**?
- Good communication?
- Very Wide ADSL
- All other ADs become wide
 - If all copied over
 - Not necessarily all, what to choose?

TRTDUR

HEIGHTBL

HEIBLGR1

HEBLGR1N

DISSTREA

WEIGHTBL

WEIBLGR1

WEBLGR1N

DISTRREA

BMIBL

BMIBLGR1

BMIBLGR1

[LAB]BL

[LAB]BL1

[LAB]BL1N

[LAB]BL2

[LAB]BL2N

OTHERS



Can we standardize?

- Yes, in structure
- Use what we have available
 - BDS
 - Supplemental structure
- Can standardize in content also
 - Gradually
 - Terminology
 - Apply Naming Convention as Terminology

ADSLSUPP

- Additional “normalized” dataset:
 - ADSLSUPP: Supplemental Subject Level Information
or
 - BDSL: Basic Data Subject Level
- Same principle as Supplemental
- Use BDS as model

ADSLSUPP

Variable Name	Variable Label	Type	CodeList / Controlled Terms	Core	Notes
STUDYID	Study Identifier	Char		Req	SDTM DM.STUDYID
USUBJID	Unique Subject Identifier	Char		Req	SDTM DM.USUBJID
PARAM	Parameter	Char		Req	The description of the analysis parameter. <i>The length cannot exceed more than 40 characters.</i>
PARAMCD	Parameter Code	Char		Req	The short name of the analysis parameter in PARAM. The length cannot exceed more than 8 characters.
PARAMN	Parameter (N)	Num		Perm	Useful for ordering and programmatic manipulation.
PARAMTYP	Parameter Type	Char	(PARAMTYP)	Perm	Indicator of whether the parameter is derived as a function of one or more other parameters. This should not be confused with DTYPE which is relevant to derived AVAL and/or AVALC values.
AVAL	Analysis Value	Num		Req (at least 1)	Numeric analysis value described by PARAM. <i>AVAL must not be filled in for records that have AVALC filled and vice versa.</i>
AVALC	Analysis Value (C)	Char			Character analysis value described by PARAM. <i>AVALC must not be filled in for records that have AVAL filled and vice versa.</i>

ADSLSUPP

DTYPE	Derivation Type	Char	(DTYPE)	Cond	Analysis value derivation method. DTYPE is used to denote, and is required to be populated, when the value of AVAL or AVALC (and thus the entire record) has been imputed, derived, or copied from other record(s). DTYPE is required to be populated even if AVAL and AVALC are null on the derived record. DTYPE is not used to denote that an analysis parameter is derived. PARAMTYP may be used to indicate that an entire parameter is derived. For each value of DTYPE, the precise derivation algorithm must be defined in analysis variable metadata, even for DTYPE values in the controlled terminology.
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ADSLSUPP

NUMCHAR	Numeric or Character	Char	(NUMCHAR: N C)	Perm	Contains N for Numeric Parameters, C for Character Parameters. Clearly identifies whether the value for the parameter is contained in AVAL (for N values of NUMCHAR) or in AVALC (for C values of NUMCHAR). The same value for the same Parameter.
DECP	Number of Decimal Places	Num		Perm	Contains an integer indicating the number of decimal places available for the value. The same for the same Parameter.
CHARLEN	Length of Character String	Num		Perm	Contains an integer indicating the length of the character string. The same for the same Parameter.

AVALTYP	Analysis Value Type	Char	(NUMCHAR: N C D T DT)	Perm	Contains N for Numeric Parameters, C for Character Parameters, D for Dates, T for Times, DT for Datetimes. Clearly identifies whether the value for the parameter is contained in AVAL (for N, D, T and DT values of NUMCHAR) or in AVALC (for C values of NUMCHAR). The same value for the same Parameter.
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ADSLSUPP is Standardized Storage

- Merge with other data is trivial
 - Subject Level $\Rightarrow$ STUDYID USUBJID
 - See paper
- All information readily available for
 - Output generation
 - Further exploration: sub setting, grouping, etc.
- Submit also?
 - Reviewer may be interested as well...

Let's talk ADaM!

- CDISC ADaM team
 - More drafts, examples
 - Hard work
 - Volunteers
- Reviewer Acceptance!?
 - SDTM for analyses?
 - Cf. Chuck Cooper's Keynote presentation
- Phuse 2011:

SDTM (10)

ADaM (6)

